Monday Morning Practice Pearls #52

I thought that a witness signature is no longer required on the information consent document but now I have an audit finding for lack of witness signature. What gives?

Effective January 21, 2019, the NIH revised its policy for the requirement for a witness to the participant's signature on the long form consent document. When using the short form consent document, a witness is still required. This policy memo can be found on the IRBO News webpage.

So, what does this mean?

- If the long form consent document (either English or fully translated) is used during the informed consent process, a witness is not required
- If the short form consent document (for non-English speaking or blind or illiterate participants) is used during the informed consent process, a witness to the oral presentation is required per regulations at 45 CFR 46.117(b)(2)
    - The witness must be present for the entire informed consent discussion/process and sign both the short form and the long form
    - While it is preferred that the interpreter serve as a witness, this is NOT required by regulation
    - If a telephone interpreter is used, another person who speaks English ***must*** be present with the investigator during the informed consent process and that person will sign as a witness

What about the "NIH Administrative Section" on the bottom of the long form and the short form?

- Select the appropriate answer on each form, depending if the interpreter served as a witness
    - An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.
    - An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is:_____.